REMARKS

Claims 61-107 are pending in the subject application. Claims 62, 63, 85, 88, 89, 93, 95 and 99 have been amended for clarification purposes and for purposes of correcting typographical errors. Claim 108 has been added. Support for the amendment to claims 62, 63, 85, 88, 89, 93, 95 and 99 and added claim 108 is found throughout the Specification, as filed, and no new matter is presented by the amendment.

Favorable reconsideration in light of the amendments and remarks which follow is respectfully requested.

1. Claim Objections

Claims 88, 89, 95, 96 and 99-106 have been objected to. The Office states:

Claim 88: A hyphen must be inserted between "self" and contained."

Claim 89: The term "can be" must be changed to "is adapted to be" for more positive recitation.

Claim 95: In line 2, "place" must be changed to "placed."

Claim 99: In line 1, "bring" must be changed to "bringing."

The claims have been amended herein as suggested. Reconsideration and withdrawal of the objections is respectfully requested.

2. 35 U.S.C. §112 Rejections

Claims 62, 63, 85 and 93 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office asserts:

Claims 62 and 93: In line 2, no antecedent basis exists for "the environment."

Claim 63: In line 2, the term "preferably" does not positively recite the limitation that follows and therefore introduces an ambiguity in the claim rendering the claim indefinite. It is not clear whether the limitation that follows "preferably" is a required feature of the claim or is merely precatory.

Claim 85: In line 2, no antecedent basis exists for "the shaft."

The claims have been amended herein in accordance with the Office's suggestions. Reconsideration and withdrawal of the 35 U.S.C. §112 rejections is respectfully requested.

3. 35 U.S.C. §102 Rejections

Claims 61-68, 70-74, 76, 79, 80, 85, 88, 89, 94, 97, 99-101 and 103-106 have been rejected under 35 U.S.C. §102(b) as being anticipated by SU733670. The Office asserts:

SU733670 discloses a surgical instrument for use in cornea removal

surgery comprising a strain gauge that detects changes in pressure from the underlying tissue during use. The detected pressure from the strain gauge is used as a control signal to change the audible tone or sound volume thereby providing audible feedback to the surgeon during use. According to English language translation of SU '670 (see attached), changes in the pressure exerted by the blade on the tissue is dynamically indicated by an associated proportional change in tone of the sound. Therefore, by monitoring such changes in pitch while cutting, the physician obtains real-time information regarding the changes in (1) tissue density, (2) tissue resistance, and (3) depth of the cut. With regard to claim 80, while a power source is not expressly stated in the reference text, a power source is implicit in the disclosure because the instrument involves taking an electrical transducer signal, amplifying it, and subsequently transforming the amplified signal to an acoustic signal. Such electrical processes necessarily require a source of electrical power.

Applicants respectfully traverse. Applicants claim, in claim 61, a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device.

The SU733670 reference, on the other hand, describes a surgical instrument having a blade wherein the instrument is capable of detecting the pressure between the blade and tissues being operated on. The instrument accomplishes this by obtaining information regarding the density of tissue, the depth of cut and the resistance of the tissue. Applicants respectfully submit that the SU733670 reference describes only the detection of static forces imparted on the device and does not describe the detection of dynamic forces on the blade as required by Applicant's claim 1.

In other words, the SU733670 reference only describes forces on the device that are stationary or fixed. The present device, on the other hand, is capable of detecting changing forces on the device as they occur.

Thus, the present device is capable of providing the user with non-visual feedback that describes the physical interactions between the surgical tool and the tissue (i.e. stress, strain, force, acceleration), electrical properties between the surgical tool and the tissue (i.e. impedance, magnetic flux) and/or spatial relations between the surgical tool and the tissue (i.e. contact, proximity).

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

It is clear from the foregoing remarks that claim 61 is not anticipated by the SU733670 reference. Claims 62-68, 70-74, 76, 79, 80, 85, 88, 89, 94, 97, 99-101 and 103-106 depend from claim 61 and, likewise, are patentable over the SU733670 reference.

Further, Applicants claim, in newly added claim 108, a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device and wherein the sensor element is capable of detecting a spatial relation of the device with the environment.

Thus, Applicants device is capable of detecting forces imparted on the device by tissues and other material in contact with the device as well as the proximity of the device with relation to the targeted area. In other words, Applicants device provides a user with feedback regarding how close the device is to the tissues prior to contact so

that the user can control movement of the device accordingly. This is particularly beneficial in delicate operations, such as operations on the eye, wherein precision is vital and application of excessive force on portions of the eye can lead to damage to the eye. Thus, for example, the device can provide a user with feedback regarding the proximity of the tip of the device (e.g. a blade) with relation to a target area of the eye so that the user can move the device as required to contact the target area more accurately, with the appropriate amount of force. This can assist the user in, for example, making the appropriate depth of a cut in the target tissues so as to cut only the required tissue and prevent cutting additional tissue and causing excessive damage.

Applicants respectfully submit that the SU733670 reference describes a device that provides feedback only as a result of contact between the device and tissue.

Accordingly, Applicants respectfully submit that claim 108 is not anticipated by the SU733670 reference.

4. 35 U.S.C. §013 Rejections

Claims 75, 81-84, 90-92 and 98

Claims 75, 81-84, 90-92, and 98 have been rejected under 35 U.S.C. §103(a) as being unpatentable over SU733670 in view of EP349443. The Office asserts:

> The claims differ from the previously cited prior art in calling for a piezopolymer element to generate an electric signal proportional to the degree of flexion. While SU '670 discloses a rigid surgical instrument, the use of surgical cutting instruments with flexible tips is conventional and well known in the art as evidenced by EP349443 noting the flexible tip which also includes a sensor which detects the degree of flexion of the tip so that the forces exerted on the tip are measured and the incision is guided more accurately. See Abstract, particularly the "USE/ADVANTAGE" section. Also, a flexible tip would enable the instrument to be introduced in difficult-to-reach areas internally. In view of EP349443, it would have been obvious to one of ordinary skill in the art to provide a flexible tip with flexion detection means in conjunction

with the previously described apparatus so that an instrument was provided that could reach difficult-to-reach internal areas via a flexible tip yet still provide a measure of the forces applied to the flexible tip during cutting.

Applicants respectfully traverse for the reasons set forth above. Namely, the SU733670 reference does not describe or suggest a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device as taught by Applicants.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 2142.

As set out above the SU733670 reference does not teach or suggest all the claim limitations. EP349443 does not remedy the deficiencies of the SU733670 reference. Rather, EP34944 describes a device that provides a measure of the pressure exerted by the device on a surface. Thus, like the SU733670 reference, EP349443 only describes forces on the device that are stationary or fixed. Further, like the SU733670 reference, EP349443 provides feedback only as a result of contact between the device and tissue. The pressure between the device and contact surface is measured and provided. Thus, EP349443 does not detect a spatial relation of the device with the environment as taught by Applicants' invention.

Accordingly, claims 61 and 108 are patentable over SU733670 in view of EP349443. Claims 75, 81-84, 90-92, and 98 depend from claim 61 and, likewise, are patentable over SU733670 in view of EP349443.

Claims 69 and 102

Claims 69 and 102 have been rejected under 35 U.S.C. §103(a) as being unpatentable over SU733670 in view of the article by Tanimoto et al entitled "Micro Force Sensor for Intravascular Neurosurgery and *In Vivo* Experiment" ("the Tanimoto article"). The Office asserts:

> The claims differ from the previously cited prior art in calling for the device to be used in neurosurgical applications. The use of devices with force-sensing capability in neurosurgical applications is conventional and well known as evidenced by the Tanimoto article...

Applicants respectfully traverse for the reasons set forth above. Namely, the SU733670 reference does not describe or suggest a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device as taught by Applicants.

The Tanimoto article does not remedy the deficiencies of the SU733670 reference. Rather, the Tanimoto article describes a catheter that measures the contact force between the catheter and blood vessels. Thus, like the SU733670 reference, the Tanimoto article only describes forces on the device that are stationary or fixed. Further, like the SU733670 reference, the Tanimoto article provides feedback only as a result of contact between the device and a surface (blood vessel). The pressure between the device and contact surface is measured and provided. Thus, the device described by the Tanimoto article does not detect a spatial relation of the device with the environment as taught by Applicants' invention.

Accordingly, claims 61 and 108 are patentable over SU733670 in view of the

Tanimoto article. Claims 69 and 102 depend from claim 61 and, likewise, are patentable over SU733670 in view of the Tanimoto article.

Claims 77, 86 and 87

Claims 77, 86 and 87 have been rejected under 35 U.S.C. §013(a) as being unpatentable over SU733670 in view of Brown et al (US4841987). The Office asserts:

> The claims differ from the previously cited prior art in calling for a microprocessor with the ability to adjust sensitivity and threshold of operation. Providing a microprocessor to process the electrical input from a force sensor in a surgical tool is conventional and well known in the art as evidenced by Brown et al (US48419870 noting microprocessors 309, 325, and 321 in Fig. 3. Moreover, potentiometers 306, 310 enable sensitivity adjustment.

Applicants respectfully traverse for the reasons set forth above. Namely, the SU733670 reference does not describe or suggest a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device as taught by Applicants.

Brown et al does not remedy the deficiencies of the SU733670 reference. Rather, Brown et al describes a force-sensing probe that measures and indicates the level of force exerted by a surface (periodontal tissue) on the probe. Thus, like the SU733670 reference, Brown et al only describes forces on the device that are stationary or fixed. Further, like the SU733670 reference, Brown et al provides feedback only as a result of contact between the device and a surface. The pressure between the device and contact surface is measured and provided. Thus, the device described by Brown et al does not detect a spatial relation of the device with the environment as taught by Applicants' invention.

Accordingly, claims 61 and 108 are patentable over SU733670 in view of Brown et al. Claims 77, 86 and 87 depend from claim 61 and, likewise, are patentable over

SU733670 in view of Brown et al.

Claims 95 and 96

Claims 95 and 96 have been rejected under 35 U.S.C. §013(a) as being unpatentable over SU733670 in view of Hall (US5411511). The Office asserts:

> The claims differ from the previously cited prior art in calling for the device to comprise a shaft and a handle wherein the sensor is placed between the shaft and the handle. Providing a force sensor between a shaft and a handle on a surgical cutting apparatus for eye surgery is conventional and well known in the art as evidenced by Hall (US5411511) noting Figs. 7 and 8 wherein sensor 30 is placed between shaft (lower portion of 25 in Fig. 70 and the "handle" 35.

Applicants respectfully traverse for the reasons set forth above. Namely, the SU733670 reference does not describe or suggest a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device as taught by Applicants.

Hall does not remedy the deficiencies of the SU733670 reference. Rather, Hall describes a device that provides the level of resistance of a surface (cornea) against a leading edge of the device. Thus, like the SU733670 reference, Hall only describes forces on the device that are stationary or fixed. Further, like the SU733670 reference, Hall provides feedback only as a result of contact between the device and a surface. The resistance between the device and contact surface is measured and provided. Thus, the device described by Hall does not detect a spatial relation of the device with the environment as taught by Applicants' invention.

Accordingly, claims 61 and 108 are patentable over SU733670 in view of Hall. Claims 95 and 96 depend from claim 61 and, likewise, are patentable over SU733670 in view of Hall.

Claim 93

Claim 93 has been rejected under 35 U.S.C. §013(a) as being unpatentable over SU733670 in view of Shan (US5728044). The Office asserts:

> The claims differ from the previously cited prior art in calling for sensing impedance or flux. However, providing strain gages to sense a change in electrical impedance responsive to flexion of a surgical tool is conventional and well known in the art as evidenced by Shan (US5728044) noting col. 6, lines 27-35 wherein an array of strain gages senses a change in electrical impedance to determine the degree of bending of a surgical tool.

Applicants respectfully traverse for the reasons set forth above. Namely, the SU733670 reference does not describe or suggest a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device as taught by Applicants.

Shan does not remedy the deficiencies of the SU733670 reference. Rather, Shan describes a visualization system that projects a three dimensional image of the device onto a video screen. Applicants, on the other hand, teach a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device.

Thus, Shan does not describe or suggest a device that detects dynamic and static forces imparted on the device and communicates these forces non-visually to a user of the device.

Accordingly, claims 61 and 108 are patentable over SU733670 in view of Shan. Claim 93 depends from claim 61 and, likewise, is patentable over SU733670 in view of Shan.

Claim 77

Claim 77 has been rejected under 35 U.S.C. §013(a) as being unpatentable over SU733670 in view of Aristides (US5928158). The Office asserts:

> The claims differ from the previously cited prior art in calling for the transducer to be attached to a grip portion of the device. Attaching speakers to the grips of surgical tools is conventional and well known in the art as evidenced by Aristides (US5928158) noting speaker 15A in Fig. 1A which emits a sound warning the surgeon when nerves are contacted.

Applicants respectfully traverse for the reasons set forth above. Namely, the SU733670 reference does not describe or suggest a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device as taught by Applicants.

Aristides does not remedy the deficiencies of the SU733670 reference. Rather, Aristides describes a device that senses and identifies nerves via naturally occurring electrical signals given off by human nerves. Aristides does not describe or suggest a device that detects dynamic and static forces imparted on the device. Further, Aristides does not detect a spatial relation of the device with the environment as taught by Applicants' invention. Rather, Aristides detects electrical signals given off by nerves.

Accordingly, claims 61 and 108 are patentable over SU733670 in view of the Aristides. Claim 77 depend from claim 61 and, likewise, are patentable over SU733670 in view of Aristides.

Claim 78

Claim 78 has been rejected under 35 U.S.C. §013(a) as being unpatentable over SU733670 in view of Epstein (US5437657). The Office asserts:

> The claims differ from the previously cited prior art in calling for the transducer to be attached to the medical practitioner using the device.

> Providing an electromechanical transducer attached to the surgeon so that audible signals are directed solely to the practitioner is conventional and well known in the art as evidenced by Epstein (US5437657) noting headphones 250 which are worn by the surgeon while using the surgical instrument during eye surgery so that an audible warning is heard by the surgeon when the correct depth is achieved.

Applicants respectfully traverse for the reasons set forth above. Namely, the SU733670 reference does not describe or suggest a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device as taught by Applicants.

Epstein does not remedy the deficiencies of the SU733670 reference. Rather, Epstein describes a device that provides feedback to a user regarding the depth of an incision being made. In particular, the device shines a light along the blade of the device during an optical procedure. The Descemet's membrane of the eye, which has a shiny surface, reflects the light. When the blade has been inserted to the proper depth, the Descemet's membrane is exposed and the light is reflected back to the user indicating that the proper depth has been reached.

Thus, Epstein does not describe or suggest a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device as taught by Applicants. Further, Epstein not describe a sensor element that is further capable of detecting a spatial relation of the device with the environment.

Accordingly, claims 61 and 108 are patentable over SU733670 in view of Epstein. Claim 78 depends from claim 61 and, likewise, are patentable over SU733670 in view of Epstein.

Claim 107

Claim 107 has been rejected under 35 U.S.C. §013(a) as being unpatentable over SU733670 in view of Steinberg et al (US5746748). The Office asserts:

> The claims differ from the previously cited prior art in calling for a sterile kit containing the device. Providing surgical cutting implements in sterile kit form is conventional and well known in the art as evidenced by Steinberg et al (US5746748) noting Figs. 9, 10 wherein a sterile kit houses the surgical implements so that a convenient, sterile, prepackaged unit was provided which precludes the need to prepare, clean, and resterilize the instruments prior to use. See col. 8, lines 43-62.

Applicants respectfully traverse for the reasons set forth above. Namely, the SU733670 reference does not describe or suggest a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device as taught by Applicants.

Steinburg et al does not remedy the deficiencies of the SU733670 reference. Rather, Steinburg et al describes a circumcision instrument that is a scissor-like instrument that includes clamping tabs. Steinburg et al does not describe or suggest a surgical device comprising a sensor element for detecting dynamic and static forces imparted on the device, wherein non-visual information relating to these forces is communicated to a user of the device as taught by Applicants. Further, Steinburg et al does not describe or suggest a device that includes a sensor element that is further capable of detecting a spatial relation of the device with the environment.

Accordingly, claims 61 and 108 are patentable over SU733670 in view of Steinburg et al. Claim 107 depends from claim 61 and, likewise, is patentable over SU733670 in view of Steinburg et al.

CONCLUSION

Applicants submit that all claims are allowable as written and respectfully request early favorable action by the Examiner.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,

Date: Aug. 25, 2003

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